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In re Application of :  
Maertens et al :  
Serial No. 09/899,303 : Decision on Petition  
Filing Date: 6 July 2001 :  
Attorney Docket no. 2551-109 :

This letter is in response to the Petition filed 21 August 2003, requesting withdrawal of the restriction requirement of 25 February 2003. The delay in acting upon this petition is regretted.

## BACKGROUND

This application was filed under 35 USC 111(a) on 6 July 2001.

The Examiner issued two restriction requirements on 25 July 2002 and 5 November 2002; Applicants responded with an election to each on 26 August 2002 and 5 December 2002, respectively.

On 25 February 2003, the Examiner issued a third Restriction requirement which vacated the previous two restriction requirements because of typographical errors. By the time this restriction requirement was set forth, Applicants had submitted four Amendments on 6 July 2001, 12 December 2001, 26 August 2002, and 5 December 2002. At the time of the third restriction requirement, Claims 67-96 were pending and divided into five groups as follows:

Group I, Claims 67-77, 79 85-91 and 95-96, drawn to recombinant vector comprising a HCV envelop protein.

Group II, Claim 78 drawn to a method for immunization.

Group II, claim 80 drawn to a host cell and recombinant protein.

Group IV, claims 81-83, 92-94 drawn to a recombinant fusion protein of HCV envelop protein.

Group V, claim 84, drawn to a method for purifying an HCV envelop protein.

Within each of Groups I, IV and V, an additional restriction requirement was made. Because the restriction between Groups II, III, IV and V is not being petition and the claims directed to those inventions have been cancelled.

For Group I, applicants were further required to elect one sequence from SEQ ID Nos. 3, 5, 7, 9, 11, 13, 21, 23, 25, 27, 29, 31, 35, 37, 41, 43, 45, 47 and 49 to be examined on merits.

Further, for Group I, applicants were required to elect one of the following vectors: Vaccinia virus, avipox virus, Ankara modified virus and baculovirus.

On 25 March, 2003, Applicants elected Group I, SEQ ID No. 7 and vaccinia virus, all with traverse.

On 21 April 2003, the Examiner sent out the first action of the merits. The Office action summary sheet states that Claims 67-70, 73-77, 79, 85-91, 95 and 96 were rejected. Claims 71, 72, 78, 80-84, 92-94, directed to non-elected inventions II, III, IV and V were withdrawn from consideration; applicants were reminded to cancel these claims. The examiner considered the traversal and made the restriction requirement final. In an attempt to set forth the scope of the subject matter under examination, the following sentence was added:

“To reflecting the examination on the scope of the vaccinia vector encoding HCV envelop protein, preferably SEQ ID No: 7, claims 67-70, 73-77, 79, 85-88 and 95-96 are considered before the examiner.”

Applicants were then reminded to “amend the claims in the scope of Vaccian vector encoding HCV envelope protein, preferable SEQ ID No. 7 for reflecting the examination on the merits.”

These confusing statements apparently contradict the Office action summary sheet, which identifies claims directed to other virus vectors as rejected.

The examiner then rejected claims 67-70, 73-74, 76-77, 79, 85-86 as indefinite under 35 USC 112, second paragraph; claims 67, 79 and 85 for lacking enablement under 35 USC 112, first paragraph; and claim 85 for lacking utility and enablement under 35 USC 101 and 112, first paragraph, respectively. Claims 70, 76 and 77 were deemed free of the prior art. Art rejections were made under 35 USC 102 or 103 for various combinations of the other claims.

On 21 August 2003, Applicants filed an amendment, which cancelled Claims 71, 72, 78, 80-84, 92-94, directed to non-elected inventions II, III, IV and V, and amended or cancelled other claims under examination. On that date, applicants also filed an Information Disclosure Statement and this petition. On 10 September 2003, a Supplemental Information Disclosure statement was filed.

## **DISCUSSION**

The file history, restriction requirements, elections and petition have been considered carefully.

Set forth below are claims 67 and 77, as pending during the first action on the merits:

67. A recombinant vector comprising a vector sequence, an appropriate prokaryotic, eukaryotic or viral promoter sequence followed by a nucleotide sequence allowing the expression of an HCV single or specifically oligomerized E1 envelope viral protein selected from the group consisting of E1 and/or E2 and/or E1/E2 viral proteins.

77. A vaccine composition comprising a recombinant vector according to claim 67.

The amendment filed 21 August 2003 cancelled claim 67 and amended claim 77 as follows:

77. A vaccine composition comprising a recombinant vector comprising a vector sequence, a promoter selected from the groups consisting of a prokaryotic promoter, a eukaryotic promoter or viral promoter, said promoter being operatively linked to a nucleic acid sequence to allow expression of an HCV single or specifically oligomerized E1 envelope viral protein.

Canceled claim 67 and both versions of the claim 77 are not limited to the elected invention, vaccinia virus vectors and HCV E1 proteins having SEQ ID No. 7. As such, claims 67 and 77, for example, should be considered linking claims. MPEP 809 states that

The linking claims must be examined with the invention elected and should any linking claim be allowed, the restriction requirement must be withdrawn. The restriction requirement of linking claims is subject to the nonallowance of the linking claims.

The Office action stated that the claims will be examined to the extent that they read upon “vaccinia vector carrying HCV E1 protein, preferably SEQ ID NO 7.” The metes and bounds of this language “preferably SEQ ID NO 7” is unclear. Had this phrase turned up in as a claim limitation, it may have warranted a rejection under 35 USC 112, second paragraph for indefiniteness. This ambiguity is compounded by the fact that claims 89, 90, and 91, directed to other non-elected vectors, were indicated as rejected in the Office action summary rather than being withdrawn from examination. Given these errors, it is unclear from the Office action which claims were examined.

The Office action stated that Claim 77, which is not limited to elected SEQ ID No. 7, nor to the elected virus type, is free of the prior art. The only rejection of claim 77 arises from a rejection under 35 USC 112, second paragraph, for being dependent upon rejected claim 67. The rejection of Claim 67 under 35 USC 112, second paragraph improperly finds the claim indefinite in view of its breadth and then asks applicants to submit a single SEQ ID No. for examination. This was improper for two reasons. First, even following a restriction requirement, Applicants are entitled to an examination of their broad linking claims. See MPEP 809.03 (and Form Paragraph 8.12). Second, claim breadth is not grounds for a rejection under 112, second paragraph, for indefiniteness. Because the examiner indicated Claim 77 as free of the prior art, and because the only rejection applied to claim 77 was improper at the time of first action on the merits, the examiner should have withdrawn the restriction requirement between the various vectors and between the various sequences and extended the examination to the full scope of Group I.

In view of the examiner's failure to follow Office procedures as outlined in MPEP 809 and the confused, protracted prosecution history, this application is being returned to the examiner to examine the full scope of the claims, as pending.

## **DECISION**

This petition has been **GRANTED** for the reasons set forth above.

The application is being returned to the examiner for consideration of the amendment and response filed 21 August 2003 and for completion of an Office action on claims as pending.

The Petition fee of \$130.00 will be credited to Applicants Deposit Account Number 14-1140, as directed.

Should there be any question with regard to this letter, please contact Special Program Examiner Julie Burke by letter addressed to the Director, Technology Center 1600, P.O. Box 1450, Alexandria VA 22313-1450 or by telephone at 703-308-7553 or by facsimile transmission at (703) 305-7230.



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